(4) Senior Associate Commissioner for Policy, Planning, and Legislation.

(h)(1) The Chief Mediator and Ombudsman and the Deputy Chief Mediator and Ombudsman are authorized to act upon requests for reconsideration of any user fee decisions under section 735 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 379h) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. These officials may not further redelegate this authority. (See subpart C, § 5.108 for the user fee-related redelegation to officials within the Center for Drug Evaluation and Research.)

(2) The Senior Associate Commissioner for Management and Systems and the Director, Office of Financial Management, are authorized to perform the functions of the Commissioner under section 736(d)(1)(c) of the act (21 U.S.C. 379h(d)(1)(C)), as amended, to waive or reduce prescription drug user fees in situation where he or she finds that ''the fees will exceed the anticipated present and future costs.'' These officials may not further redelegate this authority.

(3) The Deputy Commissioner, or in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. The User Fee Appeals Officer may not further redelegate this authority.

(i) The Senior Associate Commissioner for Management and Systems is authorized to perform all of the administrative authorities (i.e., financial, personnel, facilities management, property management, etc.) of the Commissioner. These authorities may be further redelegated, except when specifically prohibited.

(j) Unless specifically noted, the persons to whom the Commissioner has delegated authority in subparts B through L of this part may not further redelegate that authority.

§ 5.21 Emergency functions.

(a) Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his or her region to:

(1) Fully represent the Food and Drug Administration within his or her region in cooperation with the Department of Health and Human Services regional emergency plans, and

(2) Exercise the authority of the Commissioner of Food and Drugs for supervision of and direction to all Food and Drug Administration activities and use of resources within his or her region for continuity and for Federal Emergency Health Service operations.

(b) These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters. These officials may not further redelegate this authority.

§ 5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of, or extracts from, any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) The Deputy Commissioner, the Senior Associate Commissioner, the Deputy Commissioner for International and Constituent Relations, the Senior Associate Commissioner for Management and Systems, and the Senior Associate Commissioner for Policy, Planning, and Legislation.

(2) The Associate and Deputy Associate Commissioners and the Chief Counsel and Deputy Chief Counsels.

(3) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner (OC).

(4) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, OC.

(5)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).

(ii) The Director and Deputy Director, Office of Regional Operations, ORA.

(iii) The Director and Deputy Director, Office of Resource Management (ORM), ORA.

(iv) The Director, Division of Management Operations, ORM, ORA.

(v) Team Leader, FDA History Staff, ORM, ORA.

(6)(i) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC.

(ii) The Director, Division of Management Programs (DMP), OHRMS, OMS, OC.

(iii) The Chief, Dockets Management Branch, DMP, OHRMS, OMS, OC.

(7) The Associate Commissioner for Public Affairs, Office of Public Affairs (OPA), Office of the Senior Associate Commissioner (OSAC), OC.

(8)(i) The Chief Information Officer, Office of Information Resources Management (OIRM), Office of Management and Systems (OMS), OC.

(ii) The Director, Freedom of Information Staff, OIRM, OMS, OC.

(9)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Director, Office of Management, CBER.

(iii) The Director and Deputy Directors of the Office of Compliance and Biologics Quality, CBER.

(iv) The Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance, CBER.

(v) The Director and Branch Chiefs, Division of Case Management, Office of Compliance and Biologics Quality (OCBQ), CBER; and the Consumer Safety Officers, OCBQ, CBER.

(10)(i) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Management Systems, CFSAN.

(iv) The Director, Office of Cosmetics and Colors, CFSAN.

(v) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(vi) The Director, Office of Seafood, CFSAN.

(vii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(viii) The Director, Office of Special Research Skills, CFSAN.

(ix) The Director, Office of Constituent Operations, CFSAN.

(x) The Director, Office of Field Programs, CFSAN.

(xi) The Director, Office of Premarket Approval, CFSAN.

(xii) The Director, Office of Scientific Analysis and Support, CFSAN.

(11)(i) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(ii) The Associate Director and Deputy Associate Director for Management and Systems, CDRH.

(iii) The Director and Deputy Director, Office of Compliance, CDRH.

(iv) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(v) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(vi) The Director, Office of Systems and Management, CDRH.

(vii) Freedom of Information Officers, CDRH.

(12)(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Management and Communications, CVM.

(iii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iv) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(13)(i) The Director and Deputy Director for Washington Operations, National Center for Toxicological Research (NCTR).

(ii) The Deputy Center Director, Office of Management (OM), NCTR, and the Associate Director, Office of Management Services, OM, NCTR.

(iii) The Deputy Center Director, Office of Research, NCTR.

(14)(i) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, the Associate Director for Regulatory Policy, and the Associate Director for Medical Policy, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Management, CDER.

(iii) The Director and Deputy Director, Office of Compliance, CDER.

(iv) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, and the Director and Deputy Director of the Office of Biostatistics, Office of Review Management, CDER.

(v) The Directors and Deputy Directors of the Offices of Testing and Research, Generic Drugs, New Drug Chemistry, and Clinical Pharmacology and Biopharmaceutics, Office of Pharmaceutical Science, CDER.

(vi) The Director, Office of Training and Communications (OTCOM), and the Director, Division of Information Disclosure Policy, Office of Regulatory Policy, CDER.

(vii) The Directors of the Divisions of Labeling and Non-prescription Drug Compliance, Prescription Drug Compliance and Surveillance, and Manufacturing and Product Quality, Office of Compliance, CDER.

(15)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) The Director, St. Louis Branch.

(iv) The Director, Northeast Regional Laboratory, Northeast Region.

(v) The Director, Southeast Regional Laboratory, Southeast Region.

(vi) The Director, National Forensic Chemistry Center.

(vii) The Director, Arkansas Regional Laboratory.

(viii) The Director, Winchester Engineering Analytical Center.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

(1) Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; and the Senior Associate Commissioner for Policy, Planning, and Legislation.

(2) The Associate and Deputy Associate Commissioners and the Chief Counsel and Deputies.

(3) The Director and Deputy Directors, CBER; the Director and Deputy Director, CFSAN; the Director and Deputy Directors, CDRH; the Director and Deputy Director, CVM; the Director and Deputy Directors, CDER; and the Director, NCTR, the Deputy Director for Washington Operations, NCTR, and the Deputy Center Directors, Offices of Management and Research, respectively, NCTR.

(4) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner (OSAC), OC; Director, Office of Management, CBER; Director, Office of Management, CDER; Director, Office of Management Systems, CFSAN; Director, Office of Systems and Management, CDRH; Director, Office of Management and Communications, CVM; Associate Director, Office of Management Services, NCTR; and the Director, Office of Resource Management, ORA.

(5) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC.

(c) The following officials may further redelegate the authorities under paragraphs (a) and (b) of this section the Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; the Senior Associate Commissioner for Policy, Planning, and Legislation; the Associate and Deputy Associate Commissioners; the Chief Counsel and Deputy Chief Counsels; the Directors and Deputy Directors for CBER, CFSAN, CDRH, CVM, CDER, and NCTR; the Director, Office of Executive Operations, OSAC, OC; the Directors of the Offices of Management, CBER and CDER; the Director, Office of Management Systems, CFSAN; the Director, Office of Systems and Management, CDRH; the Director,

Office of Management and Communications, CVM; the Associate Director, Office of Management Services, NCTR; the Director, Office of Resource Management, ORA; and the Director, OHRMS, OMS, OC. The other officials delegated authority by this section may not further redelegate it.

(d) The Chief, Regulations Editorial Section (RES), Regulations Policy and Management Staff (RPMS), Office of Policy, Planning, and Legislation (OPPL), OC, and his or her alternates are authorized to certify true copies of FEDERAL REGISTER documents. The Chief, RES, RPMS, OPPL, OC may designate alternates as required.

§ 5.23 Disclosure of official records and authorization of testimony.

(a) The following officials are authorized to make determinations to disclose official records and information under part 20 of this chapter, except that only the officials, listed in paragraphs (a)(2) through (a)(8) of this section, have the authority under specific sections of part 20 of this chapter.

(1)(i) Deputy Commissioner, the Senior Associate Commissioner, the Deputy Commissioner for International and Constituent Relations, the Senior Associate Commissioner for Management and Systems, the Senior Associate Commissioner for Policy, Planning, and Legislation, and the Associate and Deputy Associate Commissioners.

(ii) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, Office of the Commissioner (OC).

(iii) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, OC.

(iv) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC; the Director, Division of Management Programs (DMP), OHRMS, OMS, OC; and the Chief, Dockets Management Branch, DMP, OHRMS, OMS, OC.

(v) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(vi) Regional Food and Drug Directors and District Directors.

(vii) Director, Winchester Engineering and Analytical Center.

(viii) Chiefs of branches Field/District Offices and Centers.

(ix) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(x) The Director, Office of Enforcement (OE), Office of Regulatory Affairs (ORA); Deputy Director, OE, ORA; and Director, Division of Compliance Policy, OE, ORA.

(xi) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(xii) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, the Associate Director for Medical Policy, and the Associate Director for Regulatory Policy, Center for Drug Evaluation and Research (CDER).

(xiii) The Director, Center for Devices and Radiological Health (CDRH), the Deputy Director for Regulations and Policy, and the Deputy Director for Science, CDRH.

(xiv) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(xv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(xvi) The Director, National Center for Toxicological Research (NCTR); the Deputy Center Directors, Offices of Research and Management, respectively, NCTR; and the Deputy Director for Washington Operations, NCTR.

(xvii) These officials may not further redelegate this authority.

(2) The Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA; the Director and Deputy Director, Office of Enforcement OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are delegated the authority to grant requests for testimony or to authorize the giving of testimony under § 20.1 of this chapter. These officials may not further redelegate this authority.

(3) The Associate and Deputy Associate Commissioners are delegated the authority to disclose official records